

## **R E M A R K S**

The Examiner has rejected claims 1-27 under 35 U.S.C. 102(e) as being clearly anticipated by Beebe et al., U.S. Patent No. 6,488,872 and/or McDevitt et al., U.S. Patent No. 6,589,779. As hereinafter described, applicant has amended the claims of the present application to more particularly define the invention for which protection is sought. For the reasons noted hereinafter, applicant believes the pending claims, namely, claims 1-7 and 9-27, define over the cited references and are in proper form for allowance.

Claim 1 defines a microfluidic device for displaying indicia in response to a change in a predetermined parameter of a fluid flowing therethrough. The microfluidic device includes a body defining a channel for accommodating the flow of fluid therethrough. A monitor structure is retained in the channel of the body at a user-desired position within the flow of fluid. The monitor structure displays a first indicia in response to the predetermined parameter of the fluid having the first value and a second indicia in response to the predetermined parameter of the fluid having a second value. The first and second indicias are independent of size. As hereinafter described, nothing in the cited references shows or suggests a microfluidic device wherein a monitor structure is retained at a user desired position within a channel thereof and wherein the indicias generated by the monitor structure are independent of size.

The Beebe et al. '872 patent is directed to a method of fabricating a microfluidic device. The method includes the step of providing a cartridge defining a chamber filled with a polymerizable mixture. A photomask is positioned on the top surface of the cartridge and the cartridge is exposed to ultraviolet light. The photomask corresponds to the geometry of a channel network to be formed within the microfluidic device. When polymerization is complete, residual unpolymerized polymerizable material is flushed from the cartridge to provide the channel network therein. Thereafter, structural components may be formed within the channel

utilizing the same process. As pointed out by the Examiner, one of such components includes a device that contains a responsive hydrogel. The hydrogel acts as both a sensor and an actuator that increases or decreases in size in response to a physical change or chemical change within the channel of the microfluidic device. For example, the hydrogel may contract upon exposure to an analyte of interest, thereby allowing a component in one microchannel to flow to a channel downstream thereof and mix with a second component to produce a colored change in a downstream chamber. As such, the indicia generated in response to the predetermined parameter is generated downstream of the monitor structure, and is in fact, independent of the monitor structure itself. The only indicia provided by the hydrogel disclosed in the Beebe et al. '872 patent is the change in size thereof.

With respect to McDevitt et al., 779 patent, a sensor array is provided for various uses including a determination of Ph using chemically sensitive articles attached to corresponding resin particles and confined in individually addressable wells or positions on a multi-component chip. (underlining added) However, unlike the microfluidic device of independent claim 1 wherein the monitor structure is retained in the channel of the body at a user desired position within the flow of fluid, the resin particles are free to rotate within the positions or wells on the multi-component chip. There is no teaching or suggestion to secure the resin particles within wells on the chip. Hence, it is believed that independent claim 1 defines over the McDevitt et al., '779 patent.

In view of the foregoing, it is believed that independent claim 1 defines over the cited Beebe et al., '872 patent and the cited McDevitt et al., '779 patent and is in proper form for allowance.

Referring to claims 2-6, a microfluidic device is defined wherein the monitor structure comprises a polymerized mixture including an immobilized dye. Nothing in the Beebe et al., '872 patent shows or suggests forming a monitor structure from a polymerized mixture that

includes an immobilized dye. Such a suggestion is entirely absent from the Beebe et al., '872 patent. As such, it is believed that claims 2-6, define over the Beebe et al., '872 patent. Similarly, the McDevitt et al., '779 patent does not show or suggest such a monitor structure. In the McDevitt et al., '779 patent, Ph indicators are bound to polymer beads. However, nothing in the McDevitt et al., '779 patent suggests immobilizing a dye within a polymerized mixture. The teaching or suggestion of such a structure is entirely absent from the McDevitt et al., '779 patent. As such, it is believed that claims 2-6 define over the '779 patent.

Claims 7 and 9 depend from independent claim 1 and further define a microfluidic device not shown or suggested in the prior art. It is believed that claims 7 and 9 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

Claim 10 defines a method for monitoring the environment within the microfluidic device. The method includes the steps of immobilizing a monitor structure in the channel of a microfluidic device and passing the fluid over the monitor structure. The monitor structure generates the visual display independent of size in response to a parameter of the fluid having a predetermined value.

As heretofore described with respect to independent claim 1, nothing in the Beebe et al. '872 patent shows or suggests providing a monitoring structure that generates a visual display independent of size in response to exposure to a parameter of a fluid having a predetermined value. Consequently, it is believed that independent claim 10 defines over the '872 patent.

With respect to the McDevitt et al. '779 patent, as previously described, the polymer beads are free to rotate within the confines of individually addressable wells or positions on a multi-component chip. Nothing in the McDevitt et al., '779 patent suggests immobilizing a

monitor structure within a channel of a microfluidic device. Hence, it is believed that independent claim 10 defines over the cited references and passage to allowance is respectfully requested.

It is noted that claims 11-16 include the additional step of immobilizing a dye in a polymer matrix of the monitor structure. As heretofore described, nothing in the Beebe et al. '872 patent suggests immobilizing a dye within the responsive hydrogel provided therein and nothing in the McDevitt et al., '779 patent suggests immobilizing a dye within a polymer matrix. Hence, it is believed that dependent claims 11-16 define over the cited references. Further, referring to claim 12, the method includes the additional steps of immobilizing the dye by mixing the dye in a prepolymer mixture and providing the same at the pregel. The pregel is injected into the channel of the microfluidic device and polymerized in the channel to form a monitor structure. This step is clearly not shown or suggested in either of the cited references. Consequently, applicant believes that claims 11-16 define over the cited references and are in proper form for allowance.

Claim 17 depends from independent claim 10 and further defines a method for monitoring the environment within a microfluidic device not shown or suggested in the prior art. It is believed that claim 17 is allowable as depending from an allowable base claim and in view of the subject matter of the claim.

Referring to claim 18, a method is provided for monitoring the environment within a microfluidic device. The method includes the steps of mixing the dye in a prepolymer mixture and providing the same as a pregel. Thereafter, the pregel is injected into a channel of a microfluidic device and polymerized in the channel to form a monitor structure. Fluid is past over the monitor structure in the channel such that the dye changes color in response to a parameter of the fluid having a predetermined value.

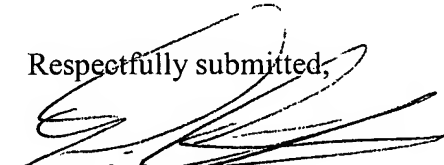
As heretofore described with respect to independent claims 1 and 10, nothing the Beebe et al., '872 patent shows or suggests steps of mixing a dye into a prepolymer mixture and injecting the prepolymer into the channel of a microfluidic device to be polymerized. Such a methodology is entirely absent from the Beebe et al., '872 patent which merely provides for a responsive hydrogel that expands and contracts in response to exposure to a predetermined parameter of a fluid. Hence, it is believed that claim 18 defines over the Beebe et al., '872 patent. With respect to the McDevitt et al., '779 patent, such reference merely discloses polymer beads having Ph indicators bound thereto. The steps of providing a prepolymer mixture and mixing a dye therein is entirely absent from the McDevitt et al., '779 patent. Further, nothing in the McDevitt et al., '779 patent suggests injecting a pregel into a channel of a microfluidic device or polymerizing the pregel in the channel. Consequently, it is believed that claim 18 also defines over the McDevitt et al., '779 patent and is in proper form for allowance.

Claims 19-27 depends either directly or indirectly from independent claim 18 and further define a method not shown or suggested in the prior art. It is believed that claims 19-27 are allowable as depending from an allowable base claim and in view of the subject matter of each claim.

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Applicant believes that the present application with claims 1-7 and 9-27 is in proper form for allowance and such action is earnestly solicited. The applicant believes that there are no fees associated with this Amendment. However, the Director is hereby authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,



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